

REMARKS

This Amendment is in response to the Office Action dated June 20, 2003. Claims 29-53 were pending in this application. By this Amendment, Applicants have canceled claims 35 and 46 and have presented them in independent form as new claims 56 and 57. Applicants have amended claim 29 to more clearly define the claimed invention. Claims 36-39, 42, 43, 47, 48, 50, 52, and 53 were amended to change the dependency of these claims in view of the canceling of claims 35 and 46. Favorable reconsideration of all of the pending claims is respectfully requested.

Applicants note that the Examiner has indicated that Claims 36-53 would be allowable if rewritten in independent form to include all of the recitations of the base claim and any intervening claim. Applicant has done so with regards to dependent Claim 46, now independent claim 57, and its dependent claims 47-53. Applicants have not rewritten the other allowable dependent claims in independent form in view of the discussion concerning claim 35 provided below.

The Examiner has rejected claims 29, 30 and 35 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,019,777 to Mackenzie (the "Mackenzie patent").

Applicants have reviewed the Mackenzie patent and note that the tubular sheath 28, which includes a distal portion 34, is utilized as a delivery device for moving a mounted stent over a balloon catheter 14 and positioning the mounted stent over an inflatable balloon 22 used to expand the stent within a body lumen. This particular use of a tubular sheath 28 in the Mackenzie patent is different from Applicants' use of the radially,

outwardly, deformable tubular sheath of the present invention. In accordance with the present invention, a tubular sheath is utilized at a site where plaque particles are formed on a vascular wall to trap the plaque once the sheath has been deployed at the site. The sheath both traps plaque against the vascular wall while creating a conduit which allows a stent or other vascular graft to extend through and out of the distal end of the sheath and be partially deployed distally from the plaque region. This is not the function of the sheath 28 described in the Mackenzie patent.

In order to clarify the claimed method, Applicants have amended claim 29 to include the recitation that the distal end of the sheath is expanded to a larger size when the step of expanding the sheath against the vascular wall, to trap the plaque therebetween, is performed. This particular step is not shown in the Mackenzie patent as the distal end 30 of the sheath 34 apparently does not expand to a larger size when the dilatation balloon 22 is inflated. Reference is made to FIG. 7-10 which shows the distal end 30 of the distal portion 34 of the sheath 28 remains unexpanded, even after expansion of the dilatation balloon 22. Again, this is because the use of the sheath in the Mackenzie patent is not to provide a conduit which allows a device, for example, a stent delivery device, to pass through the distal end of the sheath to allow the stent to be partially expanded while still preventing plaque particles from entering the bloodstream.

With reference specifically to original claim 35, now rewritten in independent form and presented as new claim 56, it is noted that the Mackenzie patent does not show the use of a radially, outward, deformable tubular member which is disposed within the

sheath as specified in the claim. Rather, the Mackenzie patent shows a stent 12 disposed or mounted on the outside surface of the distal portion 34 of the sheath 28 (see FIG. 8). Again, since the function of the distal portion 34 of the sheath 28 in the Mackenzie patent is quite different from the function of the sheath in the present invention, the Mackenzie patent fails to disclose the use of the deformable member within the sheath as recited in claim 56. In the claimed invention, the deformable member, which can be, for example, a wire mesh, a stent, or a wire coil, as specified in claims 36, 37, and 38. This deformable member is not an implantable device, as the stent 12 in the Mackenzie patent, but rather, is a structural component used to impart additional structural strength and crush resistance to the sheath, thus enabling the sheath to better support the body lumen when the implantable stent or graft is being deployed. Reference is made to Applicants' specification, namely page 13, line 7 to page 14, line 2, which describes the benefits of using such a deformable member.

The Examiner has rejected claim 31 under 35 U.S.C. § 103(a) as being unpatentable over Mackenzie in view of U.S. Patent No. 5,320,604 to Walker (the "Walker patent"). Claims 32-34 were rejected under 35 U.S.C. § 103(c) as being unpatentable over Mackenzie in view of U.S. Patent No. 5,643,278 to Wijay (the "Wijay patent"). In view of the amendment to claim 29, it is submitted that the Mackenzie patent fails to show or disclose the method as presently claimed. The teaching of the Walker patent and Wijay patent fail to provide any suggestion or teaching which would supplement the teachings of the Mackenzie patent. Accordingly, it is submitted that the

particular combination of patents relied upon by the Examiner in rejecting claims 31-34 simply do not achieve the claimed methods presented in these dependent claims.

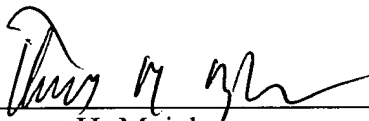
Accordingly, Applicants respectfully request the Examiner to withdraw the § 103 obviousness rejections against these pending claims.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at 310-824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: 
Thomas H. Majcher
Registration No. 31,119

THM:mjm

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201